PART C

LICENSING OF RADIOACTIVE MATERIAL

Sec. C.1 Purpose and Scope

a. This part provides for the licensing of radioactive material (NARM)[1]. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to this part or as otherwise provided in this part. However, nothing in this part shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission (source material, byproduct material and special nuclear materials).[2]

b. In addition to the requirements of this Part, all licensees are subject to the requirements of Part A, Part D, Part G, Part J, Part K, and Part T of the regulations. Licensees engaged in industrial radiographic operations are subject to the requirements of Part E and licensees using sealed sources in the healing arts are subject to the requirements of Part G of the regulations.

Sec. C.4 Exempt Radioactive Materials

a. Exempt Concentrations

i. Except as provided in C.4.a.ii., any person is exempt from this Part to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing radioactive material introduced in concentrations not in excess of those listed in Schedule A of this Part.

ii. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under C.4.a.i. or equivalent regulations of any Licensing State, except in accordance with a specific license issued pursuant to C.28 or the general license provided in C.90. General licensees are required to register with the agency.

b. Exempt Quantities

i. Except as provided in C.4.b.ii. and iii., any person is exempt from the regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Schedule B of this Part.

ii. This paragraph (C.4.b) does not authorize the production, packaging, or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

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1 The definitions of NARM, source material, byproduct material and special nuclear material are defined in A.2 of the regulations.

2 See Footnote #1.

iii. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under C.4.b. or equivalent regulations of any Licensing State, except in accordance with a specific license issued by the Agency pursuant to C.28 which license states that the radioactive material may be transferred by the licensee to persons exempt under C.4.b. or the equivalent regulations of any Licensing State.

c. Exempt Items

i. Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from the regulations to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:

(1) Timepieces provided that each timepiece does not contain more than one microcurie (37 KBq) of radium-226 in timepieces acquired prior to the effective date of the regulations; nor more than:

(a) 25 millicurie (925 MBq) of tritium per timepiece.

(b) 5 millicurie (185 MBq) of tritium per hand.

(c) 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial.

(d) 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece.

(e) 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand.

(f) 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).

(g) The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(i) For wrist watches, 0.1 millirad (1 μGy) per hour at 10 centimeters from any surface.

(ii) For pocket watches, 0.1 millirad (1 μGy) per hour at 1 centimeter from any surface.

(iii) For any other timepiece, 0.2 millirad (2 μGy) per hour at 10 centimeters from any surface.

(h) One microcurie (37 KBq) of radium-226 per timepiece in timepieces acquired prior to July 10, 2002.

ii. Electron tubes; provided, that each tube does not contain more than one microcurie (37 KBq) of lead 210. Provided further that the levels of radiation from each electron tube containing lead 210 do not exceed 1 millirad (10 μGy) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.[3]

iii. Self-Luminous Products; provided that each product does not contain more than 0.1 microcurie (3.7 KBq) of radium-226 which was acquired prior to the effective date of the regulations.

iv. Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State, provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of C.28.

v. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, a source of radioactive material not exceeding the applicable quantity set forth in Schedule B of this part.

Licenses

Sec. C.20 Types of Licenses. Licenses for radioactive materials are of two types: general and specific.

a. General licenses provided in this part are effective without the filing of applications with the Agency or the issuance of licensing documents to the particular persons, although the filing of a certificate with the Agency may be required by the particular general license. The general licensee is subject to all other applicable portions of the regulations and any limitations of the general license.

b. Specific licenses require the submission of an application to the Agency and the issuance of a licensing document by the Agency. The licensee is subject to all applicable portions of the regulations as well as any limitations specified in the licensing document.

Sec. C.22 General Licenses - Radioactive Material Other Than Source Material

a. Certain Measuring, Gauging or Controlling Devices

[3] For purposes of C.4.c.ii., "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

i. A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of C.22.a.ii, iii, and iv, radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

ii. The general license in C.22.a.i. applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the Agency pursuant to C.28 or in accordance with the specifications contained in a specific license issued by an Agreement State or a Licensing State, which authorizes distribution of devices to persons generally licensed by an Agreement State or a Licensing State.[4]

iii. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in C.22.a.i.:

(1) shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(2) shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label,

(a) devices containing not more than 100 microcuries (3.7 MBq) of other beta and/or gamma emitting material or 10 microcuries (370 KBq) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(3) shall assure that the tests required by C.22.a.iii.(2) and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(a) in accordance with the instructions provided by the labels, or

(b) by a person holding an applicable specific license from the Agency, an Agreement State or a Licensing State to perform such activities;

[4] Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(4) shall maintain records showing compliance with the requirements of C.22.a.iii.(2) and (3). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by C.22.a.iii.(2) shall be maintained for one year after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the on/off mechanism and indicator required by C.22. a.iii.(2) shall be maintained for one year after the next required test of the on/off mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by C.22.a.iii.(3) shall be maintained for a period of two years from the date of the recorded event or until the device is transferred or disposed of;

(5) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on/off mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Agency, the Agreement State or a Licensing State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Agency a report containing a brief description of the event and the remedial action taken;

(6) shall not abandon the device containing radioactive material;

(7) except as provided in C.22.a.iii.(8), shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Agency, an Agreement State or a Licensing State whose specific license authorizes him to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Agency a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

(8) shall transfer the device to another general licensee only:

(a) where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this regulation and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Agency the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Agency and the transferree; or

(b) where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and

(9) shall comply with the provisions of D.402 and D.403 of the regulations for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts D and J of the regulations.

(4) The general license in C.22.a.i. does not authorize the manufacture of devices containing radioactive material.

(5) The general license provided in C.22.a.i. is subject to the provisions of A.4 through A.9, C.31, C.40, C.50, and C.100 of the regulations.

b. Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this part, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

c. Calibration and Reference Sources

i. A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of C.22.c.ii. and iii. to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

ii. The general licenses in C.22.c.i. apply only to calibration or reference sources which have been manufactured in accordance with the manufacturer by the Agency, any Agreement State or Licensing State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32.

iii. The general licenses provided in C.22.c.i. are subject to the provisions of A.4 through A.9, C.31, C.40, C.50, C.100, Part D, and Part J of the regulations. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

(1) shall not possess at any one time, at any one location of storage or use, more than 5 microcuries (185 KBq) of radium-226 in such sources;

(2) shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

(a) The receipt, possession, use and transfer of this source, Model ____, Serial No._____, are subject to a general license and the regulations of any Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

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Name of manufacturer or importer

(3) shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Agency, an Agreement State, or a Licensing State to receive the source;

(4) shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain radium-226 which might otherwise escape during storage; and

(5) shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

iv. These general licenses do not authorize the manufacture of calibration or reference sources containing radium-226.

d. Medical Diagnostic Uses[5]

i. A general license is hereby issued to any physician to receive, possess, transfer, or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provision of C.22.d.ii, iii and iv, the radioactive material is in the form of capsules, disposable syringes, or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with a specific license issued by the Agency pursuant to C.28, any Agreement State or a Licensing State pursuant to equivalent regulations authorizing distribution to persons generally licensed pursuant to C.22.d. or its equivalent.

(1) cobalt-57 for the measurement of intestinal absorption of cyanocobalamin;

ii. No physician shall receive, possess, use, or transfer radioactive material pursuant to the general license established by C.22.d.i. until he has filed Agency Form "U," "Certificate Medical Use of Radioactive Material Under General License" with the Agency and received from the Agency a validated copy of the Agency Form "U" with certification number assigned. The generally licensed physician shall furnish on Agency Form "U" the following information and such other information as may be required by that form:

(1) name and address of the generally licensed physician

[5] C.28 requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to affix a certain identifying label to the container or in the leaflet or brochure which accompanies the radiopharmaceutical. The new drug provisions of the Federal Food, Drug and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(2) a statement that the generally licensed physician is a duly licensed physician in the practice of medicine in this State; and

(3) a statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use radioactive material under the general license of C.2.d. and that he is competent in the use of such instruments.

iii. A physician who receives, possesses or uses a pharmaceutical containing radioactive material pursuant to the general license established by C.22.d.i. shall comply with the following:

(1) He shall not possess at any one time, pursuant to the general license in C.22.d.i. more than:

(a) 5 microcuries (185 kBq) of cobalt-57.

(2) he shall store the pharmaceutical until administered in the original shipping container, or a container providing equivalent radiation protection;

(3) he shall use the pharmaceutical only for the uses authorized by C.22.d.i.;

(4) he shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age; and

(5) he shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, any Agreement State, Licensing State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

iv. The generally licensed physician possessing or using radioactive material under the general license of C.22.d.i. shall report in duplicate to the Agency, any changes in the information furnished by him in the "Certificate - Medical Use of Radioactive Material Under General License," Agency Form "U." The report shall be submitted within 30 days after the effective date of such change.

v. Any person using radioactive material pursuant to the general license of C.22.d.i. is exempt from the requirements of Part D and Part J of the regulations with respect to the radioactive material covered by the general license.

e. General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing[6]

[6] The new drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

i. A general license is hereby issued to any physician, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of C.22.e.ii., iii., iv., v, and vi, the following radioactive materials in prepackaged units:

ii. No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by C.22.e.i. until he has filed Agency Form "V," "Certificate - In Vitro Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of Agency Form "V" with certification number assigned, or until he has been authorized pursuant to C.26.c.iii. to use radioactive material under the general license in C.22.e. The physician, clinical laboratory or hospital shall furnish on Agency Form "V" the following information and such other information as may be required by that form:

(1) Cobalt-57, in units not exceeding 10 microcuries (370 KBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(2) Name and address of the physician, clinical laboratory or hospital;

(3) the location of use; and

(4) a statement that the physician, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in C.22.e.i. and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

iii. A person who receives, acquires, possesses or use radioactive material pursuant to the general license established by C.22.e.i. shall comply with the following:

(1) The general licensee shall not possess at any one time, pursuant to the general license in C.22.e.i., at any one location of storage or use, a total amount of cobalt-57 in excess of 200 microcuries (7.4 MBq).

(2) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) The general licensee shall use the radioactive material only for the uses authorized by C.22.e.i.

(4) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, any Agreement State or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from supplier.

iv. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to C.22.e.i.:

(1) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to C.28 or in accordance with the provisions of a specific license issued by any Agreement State or Licensing State which authorizes the manufacture and distribution of cobalt-57, to persons generally licensed under C.22.e. or its equivalent, and

(a) This radioactive material shall be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

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Name of Manufacturer

v. The physician, clinical laboratory or hospital possessing or using radioactive material under the general license of C.22.e.i. shall report in writing to the Agency, any changes in the information furnished by him in the "Certificate - In Vitro Testing with Radioactive Material Under General License", Agency Form "V." The report shall be furnished within 30 days after the effective date of such change.

vi. Any person using radioactive material pursuant to the general license of C.22.e.i. is exempt from the requirements of Parts D and Part J of the regulations with respect to radioactive material covered by that general license.

Sec. C.23 Intrastate Transportation of Radioactive Material

a. A general license is hereby issued to any common or contract carrier to transport and store radioactive material in the regular course of their carriage for another or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements of the regulations, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such regulations relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[7] Persons who transport and store radioactive material pursuant to the general license in this paragraph are exempt from the requirements of Part D and Part J of the regulations.

b. A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements of the regulations, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such

[7] Showing only the name of the appropriate material.

regulations relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[8]

i. Persons who transport radioactive material pursuant to the general license in C.23.b. are exempt from the requirements of Part D and Part J of the regulations to the extent that they transport radioactive material.

ii. Physicians, as defined in A.2, are exempt from the requirements of C.23.b. to the extent that they transport radioactive material for use in the practice of medicine.

Specific Licenses

Sec. C.24 Filing Application for Specific Licenses

a. Applications for specific licenses shall be filed in duplicate on a form prescribed by the Agency.

b. The Agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be amended or suspended.

c. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

d. An application for a license may include a request for a license authorizing one or more activities.

e. In his application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency provided such references are clear and specific.

f. Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

Sec. C.25 General Requirements for the Issuance of Specific Licenses. A license application will be approved if the Agency determines that:

a. the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with the regulations in such a manner as to minimize danger to public health and safety or property;

b. the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

[8] See Footnote #7.

c. the issuance of the license will not be adverse to the health and safety of the public; and

d. the applicant satisfies any applicable special requirements in C.26, C.27, or C.28.

Sec. C.26 Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material

a. Human Use of Radioactive Material in Institutions. In addition to the requirements set forth in C.25, a specific license for human use of radioactive material in institutions will be issued if:

i. the applicant has appointed a medical isotopes committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of radioactive material within that institution. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in assay of radioactive material and protection against radiation;

ii. the applicant possesses adequate facilities for the clinical care of patients;

iii. the physician designated on the application as the individual user has substantial experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and

iv. if the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses.

b. Specific Licenses to Individual Physicians for Human Use of Radioactive Material

i. An application by an individual physician or group of physicians for a specific license for human use of radioactive material will be approved if:

(1) the applicant satisfies the general requirements specified in C.25;

(2) the application is for use in the applicant's practice in an office outside a medical institution;

(3) the applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and

(4) the applicant has extensive experience in the proposed use, the handling and administration of radionuclides, and where applicable, the clinical management of radioactive patients.

ii. The Agency will not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use radioactive material on the premises of a medical institution unless:

(1) the use of radioactive material is limited to:

(a) the administration of radiopharmaceuticals for diagnostic or therapeutic purposes,

(b) the performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered,

(c) the performance of in vitro diagnostic studies, or

(d) the calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation and diagnostic instrumentation;

(2) the physician brings the radioactive material with him and removes the radioactive material when he departs. (The institution cannot receive, possess, or store radioactive material other than the amount of material remaining in the patient); and

(3) the medical institution does not hold a radioactive material license under C.26.a.

c. Specific Licenses for Certain Groups of Medical Uses of Radioactive Material

i. Subject to the provisions of C.26.c.ii., iii, and iv., an application for a specific license pursuant to C.26.a., b., or d. for any medical use or uses of radioactive material specified in one or more of Groups I to VI, inclusive, of Schedule C of this part will be approved for all of the uses within the group or groups which include the use or uses specified in the application if:[9]

(1) the applicant satisfies the requirements of C.26.a., b or d;

(2) the applicant, or the physician designated in the application as the individual user, has adequate clinical experience in the types of uses included in the group or groups;

(3) the applicant, or the physicians and all other personnel who will be involved in the preparation and use of the radioactive material, have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups;

(4) the applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups; and

[9] C.28 requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to affix a certain identifying label to the container or in the leaflet or brochure which accompanies the radiopharmaceutical.

(5) the applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups.

ii. Any licensee or registrant who is authorized to use radioactive material pursuant to one or more groups in C.26.c.i. and Schedule C of this part is subject to the following conditions:

(1) For Groups I, II, IV, and V, no licensee or registrant shall receive, possess, or use radioactive material except at a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged, and distributed in accordance with a specific license issued by the Agency pursuant to C.28 or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations.

(2) For Group III, no licensee or registrant shall receive, possess, or use generators or reagent kits containing radioactive material or shall use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:

(a) reagent kits not containing radioactive material that are approved by the Agency, an Agreement State or a Licensing State for use by persons licensed pursuant to C.26.c. and Schedule C of this part or equivalent regulations; or

(b) generators or reagent kits containing radioactive material that are manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the Agency pursuant to C.28 or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations.

(3) For Group VI, no licensee or registrant shall receive, possess, or use radioactive material except as contained in a source or device that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued to the manufacturer by the Agency pursuant to C.28 or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations.

(4) For Group III, any licensee or registrant who uses generators or reagent kits shall elute the generator or process radioactive material with the reagent kit in accordance with instructions which are approved by the Agency, an Agreement State or a Licensing State and are furnished by the manufacturer on the label attached to or in the leaflet or brochure which accompanies the generator or reagent kit.

(5) For Group VI any licensee who possesses and uses sources or devices containing radioactive material shall:

(a) cause each source or device containing more than 100 microcuries (3.7 MBq) of radioactive material with a half-life greater than 30 days, to be tested for contamination and/or leakage at intervals not to exceed 6 months or at such other intervals as are approved by the Agency, an Agreement State or a Licensing State and described by the manufacturer on the label attached to the source, device, or permanent container thereof, or in the leaflet or brochure which accompanies the source or device. Each source or device shall be so tested prior to its first use unless the supplier furnishes a certificate that the source or device has been so tested within six months prior to the transfer;

(b) assure that the test required by C.26.c.ii.(5)(a) shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample or in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) per 24 hours. The test sample shall be taken from the source or from the surfaces of the device in which the source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Agency;

(c) if the test required by C.26.c.ii.(5)(a) reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination or in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) per 24 hours, immediately withdraw the source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with Agency regulations. A report shall be filed within 5 days of the test with the Agency, describing the equipment involved, the test results, and the corrective action taken;

(d) follow the radiation safety and handling instructions approved by the Agency, an Agreement State or a Licensing State and furnished by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and maintain such instruction in a legible and conveniently available form;

(e) conduct a quarterly physical inventory to account for all sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of the inventory;

(f) assure that needles or standard medical applicator cells containing radium-226, are not opened while in the licensee's possession unless specifically authorized by a license issued to him by the Agency; and

(g) assure that patients containing radium-226 implants shall remain hospitalized until the implants are removed.

iii. Any licensee who is licensed pursuant to C.26.c.i. for one or more of the medical use groups in Schedule C also is authorized to use radioactive material under the general license in C.22.e. for the specified in vitro uses without filing Form V as required by C.22.e.ii.; provided, that the licensee is subject to the other provisions of C.22.e.

iv. Any licensee who is licensed pursuant to C.26.c.i. for one or more of the medicine use groups in Schedule C also is authorized, subject to the provisions of C.26.c.iv. and v., to receive, possess, and use for calibration and reference standards:

(1) any radioactive material listed in Group I, Group II, or Group III of Schedule C of this part with a half-life not longer than 100 days, in amounts not to exceed 15 millicuries (555 MBq) total;

(2) any radioactive material listed in Group I, Group II, or Group III of Schedule C of this part with half-life greater than 100 days in amounts not to exceed 200 microcuries (7.4 MBq) total;

(3) any radioactive material, in amounts not to exceed 3 millicuries (111 MBq) per source, contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the Agency pursuant to C.28, or a specific license issued to the manufacturer by an Agreement State or a Licensing State pursuant to equivalent regulations.

v. Any licensee or registrant who possesses sealed sources as calibration or reference sources pursuant to C.26.c.iv. shall cause each sealed source containing radioactive material, with a half-life greater than 30 days in any form other than gas to be tested for leakage and/or contamination at intervals not to exceed 6 months.

(1) In the absence of a certificate from a transferor indicating that a test has been made within 6 months prior to the transfer, the sealed sources should not be used until tested, provided, however, that no leak tests are required when:

(a) the source contains 100 microcuries (3.7 MBq) or less of beta and/or gamma emitting material or 10 microcuries (370 KBq) or less of alpha emitting material, or

(b) the sealed source is stored and is not being used; such sources shall, however, be tested for leakage prior to any use or transfer unless they have been leak tested within 6 months prior to the date of use or transfer.

(2) The leak test shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which contamination might be expected to

accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Agency.

(3) If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee or registrant shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Parts C and D of the regulations. A report shall be filed within five days of the test with the Agency describing the equipment involved, the test results, and the corrective action taken.

vi. Any licensee or registrant who possesses and uses calibration and reference sources pursuant to C.26.c.iv.(3) shall:

(1) follow the radiation safety and handling instructions approved by the Agency, an Agreement State or a Licensing State and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instruction in a legible and conveniently available form; and

(2) conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sources, and the date of the inventory.

d. Human Use of Sealed Sources. In addition to the requirements set forth in C.25, a specific license for human use of sealed sources will be issued only if the applicant or, if the application is made by an institution, the individual user:

i. has specialized training in the diagnostic or therapeutic use of the sealed source considered, or has experience equivalent to such training and

ii. is a physician.

Sec. C.27 - Special Requirements for Specific Licenses of Broad Scope. This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses.[10]

a. The different types of broad scope licenses are set forth below:

i. A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in

[10] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the NRC, Washington, D.C. 20555.

the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

ii. A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Schedule D of this Part, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

iii. A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in Schedule D of this Part, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

b. An application for a Type A specific license of broad scope will be approved if:

i. the applicant satisfies the general requirements specified in Section C.25;

ii. the applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

iii. the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(1) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

(2) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(3) the establishment of appropriate administrative procedures to assure:

(a) control of procurement and use of radioactive material;

(b) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(c) review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with Subdivision C.27b.iii.(3)(b) prior to use of the radioactive material.

c. An application for a Type B specific license of broad scope will be approved if:

i. the applicant satisfies the general requirements specified in Section C.25; and

ii. the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(1) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

(2) the establishment of appropriate administrative procedures to assure,

(a) control of procurement and use of radioactive material,

(b) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and

(c) review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with Subdivision C.27c.ii.(2)(b) prior to use of the radioactive material.

d. An application for a Type C specific license of broad scope will be approved if:

i. the applicant satisfies the general requirements specified in Section C.25;

ii. the applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(1) a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering, and

(2) at least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

iii. the applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

e. Specific licenses of broad scope are subject to the following conditions:

i. Unless specifically authorized, persons licensed pursuant to Section C.27 shall not:

(1) conduct tracer studies in the environment involving direct release of radioactive material;

(2) receive, acquire, own, possess, use, or transfer devices containing 100,000 (3.7 PBq) curies or more of radioactive material in sealed sources used for irradiation of materials;

(3) conduct activities for which a specific license issued by the Agency under Sections C.26, C.28 of the regulations is required; or

(4) add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

ii. Each Type A specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

iii. Each Type B specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

iv. Each Type C specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of Paragraph C.27d.

Sec. C.28 Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products or Devices Which Contain Radioactive Material. Under authority of Section 7405 of the Act, the Authority adopts as the official Special Requirements for a Specific License to

Manufacturer, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material, Sec. C.28 of Part C. SSRCR (also refer to 10 CFR 32).

a. Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations

i. In addition to the requirements set forth in Section C.25, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under Subparagraph C.4a.i. will be issued if:

(1) the applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

(2) the applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Schedule A of this Part, that reconcentration of the radioactive material in concentrations exceeding those in Schedule A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

ii. Each person licensed under Paragraph C.28a. shall file an annual report with the Agency which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to Paragraph C.28a. during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

b. Licensing the Distribution of Radioactive Material in Exempt Quantities[11]

i. An application for a specific license to distribute NARM to persons exempted from the regulations pursuant to Paragraph C.4b. will be approved if:

(1) the radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(2) the radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(3) the applicant submits copies of prototype labels and brochures and the Agency approves such labels and brochures.

ii. The license issued under Subparagraph C.28b.i. is subject to the following conditions:

(1) No more than 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

(2) Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to Paragraph C.4b. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5 μSv) per hour.

(3) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

(a) identifies the radionuclide and the quantity of radioactivity, and

(a) bears the words "Radioactive Material".

(4) In addition to the labeling information required by Subdivision C.28.b.ii.(3), the label affixed to the immediate container, or an accompanying brochure, shall:

[11] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the NRC, Washington, D.C. 20555.

(a) state that the contents are exempt from Licensing State requirements,

(b) bear the words "Radioactive Material - Not for Human Use - Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited--Exempt Quantities Should Not Be Combined", and

(c) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

iii. Each person licensed under Paragraph C.28b. shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under Paragraph C.4b. or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Agency. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to Paragraph C.28b. during the reporting period, the report shall so indicate.

c. Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under Subparagraph C.4c.iii. will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie (3.7 kBq).

d. Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under Paragraph C.22d.

i. An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under Paragraph C.22d. or equivalent regulations of the NRC, an Agreement State, or a Licensing State will be approved if:

(1) the applicant satisfies the general requirements of Section C.25;

(2) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(a) the device can be safely operated by persons not having training in radiological protection,

(b) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of 1 calendar quarter a dose in excess of 10 percent of the limits specified in the table in Paragraph D.101.a. of the regulations, and

(c) under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 rems (150 mSv)
Hands and forearms; feet and ankles; Localized areas of skin averaged over areas no larger than 1 square centimeter	200 rems (2 Sv)
Other organs and	50 rems (500 mSv);

(3) each device bears a durable, legible, clearly visible label or labels approved by the Agency, which contain in a clearly identified and separate statement:

(a) instructions and precautions necessary to assure safe installation, operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information,

(b) the requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity, and

(c) the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(i) The receipt, possession, use, and transfer of this device, Model __, Serial No. _____ [12], are subject to a general license or the equivalent and the regulations of the NRC or a State with which the NRC has entered into an agreement for the exercise of

[12] The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

(ii) The receipt, possession, use, and transfer of this device, Model __, Serial No. _____ [13], are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

ii. In the event the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency will consider information which includes, but is not limited to:

(1) primary containment or source capsule;

(2) protection of primary containment;

(3) method of sealing containment;

(4) containment construction materials;

(5) form of contained radioactive material;

(6) maximum temperature withstood during prototype tests;

(7) maximum pressure withstood during prototype tests;

(8) maximum quantity of contained radioactive material;

[13] See Footnote 12.

(9) radiotoxicity of contained radioactive material; and

(10) operating experience with identical devices or similarly designed and constructed devices.

iii. In the event the applicant desires that the general licensee under Paragraph C.22d., or under equivalent regulations of the NRC, an Agreement State, or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10 percent of the limits specified in the table in Paragraph D.101.a. of the regulations.

iv. Each person licensed under Paragraph C.28d. to distribute devices to generally licensed persons shall:

(1) furnish a copy of the general license contained in Paragraph C.22d. to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in Paragraph C.22.d.;

(2) furnish a copy of the general license contained in the NRC's, Agreement State's, or Licensing State's regulation equivalent to Paragraph C.22d., or alternatively, furnish a copy of the general license contained in Paragraph C.22d. to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the NRC, the Agreement State, or the Licensing State. If a copy of the general license in Paragraph C.22d. is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the NRC, Agreement State, or Licensing State under requirements substantially the same as those in Paragraph C.22d.;

(3) report to the Agency all transfers of such devices to persons for use under the general license in Paragraph C.22d. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under Paragraph C.22d.

during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter;

(4) furnish reports to other agencies.

(a) Report to the NRC all transfers of such devices to persons for use under the NRC general license in Section 31.5 of 10 CFR Part 31.

(b) Report to the responsible State agency all transfers of devices manufactured and distributed pursuant to Paragraph C.28d. for use under a general license in that State's regulations equivalent to Paragraph C.22d.

(c) Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.

(d) If no transfers have been made to NRC licensees during the reporting period, this information shall be reported to the NRC.

(e) If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State agency upon request of that agency; and

(5) keep records showing the name, address, and the point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in Paragraph C.22.d., or equivalent regulations of the NRC, an Agreement State, or a Licensing State. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of Subparagraph C.28d.iv.

e. Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under Paragraph C.22e. will be approved if:

i. the applicant satisfies the general requirements specified in Section C.25; and

ii. the applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, and 32.101 of 10 CFR Part 32, or their equivalent.

f. Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under Paragraph C.22g. An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under Paragraph C.22g. will be approved if:

i. the applicant satisfies the general requirement of Section C.25; and

ii. the applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

g. Reserved

h. Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of Paragraph C.22i. will be approved if:

i. the applicant satisfies the general requirements specified in Section C.25.

ii. the radioactive material is to be prepared for distribution in prepackaged units of:

(1) carbon-14 in units not exceeding 10 microcuries (370 kBq) each.

(2) cobalt-57 in units not exceeding 10 microcuries (370 kBq) each.

(3) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

(4) iodine-125 in units not exceeding 10 microcuries (370 kBq) each.

(5) Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

(6) iodine-131 in units not exceeding 10 microcuries (370 kBq) each.

(7) iron-59 in units not exceeding 20 microcuries (740 kBq) each.

(8) selenium-75 in units not exceeding 10 microcuries (370 kBq) each.

iii. each prepackaged unit bears a durable, clearly visible label:

(1) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50

microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and

(2) displaying the radiation caution symbol described in Subparagraph D.203a.i. and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

iv. one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(1) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for <u>in vitro</u> clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority.

_____

Name of manufacturer

(2) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for <u>in vitro</u> clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a Licensing State.

_____

Name of manufacturer

v. the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in Section D.301 of the regulations.

i. <u>Licensing the Manufacture and Distribution of Ice Detection Devices.</u> An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under Paragraph C.22.j. will be approved if:

i. the applicant satisfies the general requirements of Section C.25; and

ii. the criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32 are met.

j. Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Group Licenses. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to this Part for the uses listed in Sections G.30, G.32, and G.36 of the regulations will be approved if:

i. the applicant satisfies the general requirements specified in Section C.25 of this Part;

ii. the applicant submits evidence that:

(1) the radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

(2) the manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

iii. the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and

iv. (1) the label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Agency for distribution to persons licensed pursuant to this Part for the uses listed in Sections G.30, G.32, and G.36 of the regulations or under equivalent licenses of the NRC, an Agreement State, or a Licensing State.

(2) the labels, leaflets, or brochures required by Subdivision C.28.j.iv.(1) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

k. Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.[14] An application for a specific license

[14] Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do

to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to this Part for the uses listed in Section G.32 of the regulations will be approved if:

i. the applicant satisfies the general requirements specified in Section C.25;

ii. the applicant submits evidence that:

(1) the generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

(2) the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

iii. the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

iv. the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

v. the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(1) adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

(2) a statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Agency pursuant to Section G.32 of the regulations or under equivalent licenses of the NRC, an Agreement State, or a Licensing State. The labels, leaflets, or brochures required by Paragraph C.28.k. are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

l. Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part G for use as a calibration or reference source or for the uses listed in Sections G.40 and G.42 of the regulations will be approved if:

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not contain radioactive material who desires to have his reagent kits approved by the Agency for use by persons licensed pursuant to Section G.32 of the regulations may submit the pertinent information specified in Paragraph C.28k.

i. the applicant satisfies the general requirements in Section C.25 of this Part;

ii. the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(1) the radioactive material contained, its chemical and physical form, and amount,

(2) details of design and construction of the source or device,

(3) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(4) for devices containing radioactive material, the radiation profile of a prototype device,

(5) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(6) procedures and standards for calibrating sources and devices,

(7) legend and methods for labeling sources and devices as to their radioactive content, and

(8) instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

iii. the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the Agency for distribution to persons licensed pursuant to Part G and Sections G.40 and G.42 of the regulations or under equivalent licenses of the NRC, an Agreement State, or a Licensing State, provided that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

iv. in the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than 6 months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

v. in determining the acceptable interval for test of leakage of radioactive material, the Agency will consider information that includes, but is not limited to:

(1) primary containment or source capsule,

(2) protection of primary containment,

(3) method of sealing containment,

(4) containment construction materials,

(5) form of contained radioactive material,

(6) maximum temperature withstood during prototype tests,

(7) maximum pressure withstood during prototype tests,

(8) maximum quantity of contained radioactive material,

(9) radiotoxicity of contained radioactive material, and

(10) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

m. Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications

i. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to Paragraph C.21.d or equivalent regulations of the NRC or an Agreement State will be approved if:

(1) the applicant satisfies the general requirements specified in Section C.25;

(2) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of 1 calendar quarter a radiation dose in excess of 10 percent of the limits specified in Paragraph D.201.a. of the regulations; and

(3) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

ii. In the case of an industrial product or device whose unique benefits are questionable, the Agency will approve an application for a specific license under Paragraph C.28 only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

iii. The Agency may deny any application for a specific license under Paragraph C.28 if the end use(s) of the industrial product or device cannot be reasonably foreseen.

iv. Each person licensed pursuant to Subparagraph C.28 shall:

(1) maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(2) label or mark each unit to:

(a) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(b) state that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the NRC or an Agreement State;

(3) assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(4) (a) furnish a copy of the general license contained in Paragraph C.21.d. and a copy of Agency Form W to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in Paragraph C.21.d., or

(b) furnish a copy of the general license contained in the NRC's or Agreement State's regulation equivalent to Paragraph C.21.d. and a copy of the NRC's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in Paragraph C.21.d. and a copy of Agency Form W to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the NRC or an Agreement State, with a note explaining that use of the product or device is regulated by the NRC or an Agreement State under requirements substantially the same as those in Paragraph C.21.d.;

(5) report to the Agency all transfers of industrial products or devices to persons for use under the general license in Paragraph C.21.d. Such report shall identify each

general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under Paragraph C.21.d. during the reporting period, the report shall so indicate;

(6) (a) report to the NRC all transfers of industrial products or devices to persons for use under the NRC general license in Section 40.25 of 10 CFR Part 40,

(b) report to the responsible State agency all transfers of devices manufactured and distributed pursuant to Paragraph C.28.m. for use under a general license in that State's regulations equivalent to Paragraph C.21.d.,

(c) such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person,

(d) if no transfers have been made to NRC licensees during the reporting period, this information shall be reported to the NRC, and

(e) if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon the request of that agency; and

(7) keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in Paragraph C.21.d. or equivalent regulations of the NRC or an Agreement State. The records shall be maintained for a period of 2 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this Section.

Sec. C.30 Issuance of Specific Licenses

a. Upon a determination that an application meets the requirements of the Act and the regulations of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

b. The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

i. minimize danger to public health and safety or property;

ii. require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

iii. prevent loss or theft of material subject to this part.

Sec. C.31 Specific Terms and Conditions of Licenses

a. Each license issued pursuant to this Part shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

b. No license issued or granted under this Part and no right to possess or utilize radioactive material granted by any license issued pursuant to this Part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations, and orders of the Agency, and shall give its consent in writing.

c. Each person licensed by the Agency pursuant to this Part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

d. Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

e. Each licensee shall notify the Agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

i. the licensee;

ii. an entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

iii. an affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

f. The notification specified in Paragraph C.31.e. shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

Sec. C.32 Expiration and Termination of Licenses

a. Except as provided in C.33.b., each specific license shall expire at the end of the specified day in the month and year stated therein.

b. Each licensee shall notify the Agency immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving radioactive material authorized under the license. This notification and request for termination of the license must include the reports and information specified in Subdivisions C.32.d.i.(4) and (5).

c. No less than 30 days before the expiration date specified in the license, the licensee shall either:

   i. submit an application for license renewal under Section C.33; or

   ii. notify the Agency, in writing, if the licensee decides not to renew the license.

d. i. If a licensee does not submit an application for license renewal under Section C.33, the licensee shall, on or before the expiration date specified in the license:

      (1) terminate use of radioactive material;

      (2) remove radioactive contamination to the extent practicable;

      (3) properly dispose of radioactive material;

      (4) submit a completed Agency Form T; and

      (5) submit a radiation survey report to confirm the absence of radioactive material or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The licensee shall, as appropriate:

         (a) report levels of radiation in units of microrads or nano grays (nGy) per hour of beta and gamma radiation at 1 centimeter and gamma radiation at 1 meter from surfaces and report levels of radioactivity, including alpha, in units of transformations per minute (or microcuries (μCi) or becquerels (Bq)) per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete; and

         (b) specify the instrumentation used and certify that each instrument was properly calibrated and tested.

   ii. If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. The Agency will notify the licensee, in writing, of the termination of the license.

iii. (1) If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the Agency notifies the licensee in writing that the license is terminated. During this time the licensee is subject to the provisions of Paragraph C.32.e.

(2) In addition to the information submitted under Subdivisions C.32.d.i.(4) and (5), the licensee shall submit a plan for decontamination, if required, as regards residual radioactive contamination remaining at the time the license expires.

e. Each licensee who possesses residual radioactive material under Subparagraph C.32.d.iii., following the expiration date specified in the license shall:

i. limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

ii. continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Agency notifies the licensee in writing that the license is terminated.

Sec. C.33 Renewal of Licenses

a. Applications for renewal of specific licenses shall be filed in accordance with Section C.24.

b. In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Agency.

Sec. C.34 Amendment of Licenses at Request of Licensee. Applications for amendment of a license shall be filed in accordance with Section C.24 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

Sec. C.35 Agency Action on Applications to Renew or Amend. In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in Sections C.25, C.26, C.27, and C.28 and in Part E of the regulations, as applicable.

Sec. C.37 Persons Possessing Naturally Occurring and Accelerator-Produced Radioactive Material (NARM) on effective date of the regulations. Any person who, on the effective date of the regulations, possesses NARM for which a specific license is required by the Act or this Part shall be deemed to possess such a license issued under the Act and this Part. Such license shall expire 30 days after the effective date of the regulations; provided, however, that if within the 30 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the Agency.

Transfer of Material

Sec. C.40 - Transfer of Material

a. No licensee shall transfer radioactive material except as authorized pursuant to Section C.40.

b. Except as otherwise provided in his license and subject to the provisions of Paragraphs C.40.c. and d., any licensee may transfer radioactive material:

   i. to the Agency;[15]

   ii. to the U.S. Department of Energy;

   iii. to any person exempt from the regulations to the extent permitted under such exemption;

   iv. to any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Agency, the NRC, any Agreement State or any Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Agency, an Agreement State, or a Licensing State; or

   v. as otherwise authorized by the Agency in writing.

c. Before transferring radioactive material to a specific licensee of the Agency, the NRC, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Agency, the NRC, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

d. Any of the following methods for the verification required by Paragraph C.40.c. are acceptable:

   i. The transfer or may possess and read a current copy of the transferee's specific license or registration certificate.

   ii. The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

   iii. For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within 10 days.

[15] A licensee may transfer material to the Agency only after receiving prior approval from the Agency.

iv. The transferor may obtain other information compiled by a reporting service from official records of the Agency, the NRC, an Agreement State, or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration.

v. When none of the methods of verification described in Subparagraphs C.40.i. through iv. are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Agency, the NRC, or an Agreement State, or a Licensing State prior that the transferee is licensed to receive the radioactive material.

e. Shipment and transport of radioactive material shall be in accordance with the provisions of Part T of the regulations.

Modification and Revocation of Licenses

Sec. C.50 Modification, and Revocation of Licenses

a. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the Agency.

b. Any license may be suspended or amended, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, records, or inspection or other means which would warrant the Agency to refuse to grant a license or an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, regulation, or order of the Agency.

c. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

d. The Agency may terminate a specific license upon request submitted by the licensee to the Agency in writing.

Reciprocity

Sec. C.90 Reciprocal Recognition of Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material

a. Subject to the regulations, any person who holds a specific license from any Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:

i. the licensing document does not limit the activity authorized by such document to specified installations or locations;

ii. the out-of-state licensee notifies the Agency in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in C.90.a.;

iii. the out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Agency;

iv. the out-of-state licensee supplies such other information as the Agency may request; and

v. the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in C.90.a.i. except by transfer to a person:

(1) specifically licensed by the Agency or by another Licensing State to receive such material, or

(2) exempt from the requirements for a license for such material under C.4.

b. Notwithstanding the provisions of C.90.a., any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in C.22.a.i. within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in this State provided that:

i. Such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

ii. the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Licensing State.

iii. such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

iv. the holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in Paragraph C.22.d.

c. The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.